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10/081,050	02/20/2002	David W. Osborne	1195.346US1	2420
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SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				CHANNAVAJJALA, LAKSHMI SARADA
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,050	Applicant(s) OSBORNE, DAVID W.
	Examiner Lakshmi S. Channavajjala	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 August 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,4,7-22,27-29 and 31 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,4,7-22,27-29 and 31 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 5-30-08 and 8-12-08

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date, _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Receipt of amendment, response and IDS all dated 8-12-08 and IDS dated 5-30-08 is acknowledged.

Claims 1, 4, 7-22, 27-29 and 31 are pending. Claims 2-3, 5-6, 23-26 and 30 are canceled.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 4, 7, 13, 14, 20, 21, 27-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 ('085) to Osborne or US 5,863,560 ('560) to Osborne (as evidenced by Russell, AFP, 2000).

Instant claim 1 recites a method for reducing the number of non-inflammatory acne lesions comprising the step of topically applying a composition consists

essentially of dapsone. Claim 25 is directed to a method of treating non-

inflammatory acne lesions comprising the step as in claim 1.

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the

composition is effective with dapsone as an active agent (col. 3 of '085 and '560).

Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapson, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapson concentration. Both references disclose dapson in a topical composition and for the same purpose i.e., treatment of acne.

Russell teaches that acne, usually diagnosed by the patient, is of three type i.e., inflammatory acne, non-inflammatory acne or a mixture of both (inflammatory and non-inflammatory) types and that the most common situation of acne is a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While '085 and '560 does not disclose treatment of non-inflammatory acne, nothing in the above references indicate that acne (treated by Dapsone of '085 or '560) is not the commonly occurred form (as taught by Russell) and that the acne lesions are only of inflammatory type. Accordingly, both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of '060 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of '085 and '560.

2. Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21, 27-29 and 31 above, and further in view of US 6,200,964 to Singleton et al OR

over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of in view of Russell and US 6,200,964 to Singleton et al.

'085 and '560 fail to teach the claimed cream, lotion, spray, suspension and ointment formulations. The above references also fail to teach 5% dapsone. Russell suggests preparation of acne treatment formulations in the form of a gel, ointment or cream depending on the patient's skin type (page 3).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '085 or '560 in the form of a spray, lotion or a cream or an ointment, depending the type of the skin of the patient being treated because '964 teaches acne preparations in any of the above forms and Russell suggests creams are appropriate for dry skin, gels for oily skin, lotions for any skin type and solutions fro dissolved topical antibiotics. Accordingly, it would have been within the scope of a skilled artisan to optimize the amount of dapsone (of '085 and '560) and choose the type of the formulation i.e., a gel or a lotion or a cream

etc., depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions- both types).

Response to Arguments

Applicant's arguments filed 8-12-08 have been fully considered but they are not persuasive.

Rejection of claims under 35 USC 102(b):

Claims 1, 4, 7, 13, 14, 20, 21, 27-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Applicants argue that the Examiner's theory of inherency is misapplied and that if topical dapsonic of Osborne had actually been used to treat inflammatory acne, the examiner would be correct in stating that dapsonic (of Osborne) would inherently treat non-inflammatory acne. It is argued that there was no actual use of dapsonic by Osborne in treating any kind of acne, and therefore inherency cannot attach. In this regard, applicants state the two general principles for inherency that require actual use i.e., alleged feature necessarily occurs each and every time the prior art composition or method is used and that the newly discovered feature is inherent if the applicant claims the same use described for a prior art composition or method but asserts patentability by additionally claiming the new feature of that composition or method. It is argued that the inherent feature must be present every time the prior art method or composition is

used and because Osborne never used topical dapsone in treatment, it could inherently treat non-inflammatory acne every time it is used.

Applicants' arguments are not persuasive because in contrast to what is argued, Osborne clearly states that the composition is specifically used to treat inflammatory acne. The courts have concluded that applicant need not have actually reduced the invention to practice prior to filing. *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). This, together with the fact that Osborne (admittedly) teaches dapsone for treat inflammatory acne only supports the two principles of inherency cited (above) by applicants. More specifically, the old method of treating inflammatory acne with dapsone (Osborne) anticipates the claimed new use of treating non-inflammatory acne. Secondly, the fact that Osborne anticipates claimed method is supported by *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) which states that actual use is not required when a reference teaches the composition or method.

Applicants argue that *Gould v. Quigg*, 822 F.2d 1074, 1078 situation only applied to enablement rejection and not to anticipation rejection and further states that Osborne is enabled to treat inflammatory acne. With respect to the argument regarding the enablement of the teachings of Osborne, if applicants emphasize that it is not an enablement issue, then examiner once again reiterates that every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (*Metropolitan Eng. Co. v. Coe*, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935) and that applicants need not have actually reduced the invention to practice prior to filing.

Applicants argue that patent law on inherency generally relies on a fundamental, but not articulated presumption of actual use and cite the case laws In re May, In re Crish, In re Best, and In re Cruciferous Sprout Litigation to support this position. Applicants argue “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). However, the argument is not persuasive because the courts held that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). This combined with the Gould v. Quigg, 822 F.2d 1074, 1078 and Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935) supports the examiner’s position regarding inherency of the claimed method.

Applicants argue that it would be impossible for non-inflammatory acne to be necessarily treated each and every time the prior art dapsone were used because the reference does not actually treat any skin condition and instead only tests the permeability and retention properties of the compound in cadaver skin. This argument is not persuasive because the preferred embodiment of Osborne is directed to topical application of the composition to treat acne (abstract). Osborne describes that antibiotic such as dapsone requires highly efficient penetration and delivery into pilosebaceous unit without crossing stratum corneum (col. 2, L 5-18). Osborne clearly states topical

application of the dapsone gel for acne lesions (col. 8, L 1-12). Applicants did not show that the lesions described by Osborne do not include non-inflammatory lesions. Further, instant claims do not exclude the presence of inflammatory and non-inflammatory lesions, which according to Russell et al is a typical situation in acne (i.e., a mixture of inflammatory and non-inflammatory). In this regard, Osborne references teach the “treating inflammatory acne”, which can be construed as the usual and normal operation and that dapsone treats non-inflammatory acne is inherent to the above teachings. Further, applicants have not provided any experimental evidence to contradict the teachings of Osborne that dapsone is effective in treating inflammatory acne. With respect to the opinion declaration of Robert Lathrop (submitted in response to the action dated 3-16-04), applicants do not deny the fact that the most common forms of acne comprises both inflammatory and non-inflammatory. Thus, a treatment of inflammatory acne inherently provides an effective treatment for non-inflammatory acne. SmithKline Beecham Corp. v.Apotex Corp., 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound “inherently” anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate). With respect to the limitation of claim 31, “identifying non-inflammatory acne”, it is argued that the limitation is not inherent to Osborne. However, it is clear from the evidence of Russell and also the description in col. 1-2 of Osborne that non-inflammatory lesions co-exist and also develop into

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inflammatory lesions and therefore a treatment of inflammatory lesions necessarily includes non-inflammatory lesions.

Obviousness rejection:

Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21, 27-29 and 31 above, and further in view of US 6,200,964 to Singleton et al.

With respect to the rejection of claims 8-12 and 15-19 as being unpatentable over Osborne in view of Russell and Singleton, applicants argue that examiner improperly carried over the inherency argument and the inherency doctrine has no place in determining the obviousness of a new use of an old compound. Applicants reiterate that there is no inherent ability of dapson to reduce non-inflammatory acne, which precludes a finding of obviousness under 35 USC 103.

Applicants argue that instant claims are directed to a method and not composition claims. It is argued that the dependent claims reciting the spray, cream and lotion include all of the limitations of the independent claims. It is argued that Russell and Singleton fail to disclose dapson and that nothing in Osborne or the knowledge generally available in the art would lead one to treat non-inflammatory acne with dapson and instead teach away. Therefore, it is argued that there is no suggestion or motivation to combine the teachings to use dapson for non-inflammatory acne, and there would be no reasonable expectation of success in reducing non-inflammatory

lesions. Applicants' arguments regarding the inherent ability of dapson to reduce non-inflammatory acne have been adequately addressed in the previous paragraphs.

Applicants state that inherency has no place in obviousness and cites

However, the argument is not persuasive because the arguments regarding the inherency have been addressed above and the combination of instant references is to provide the motivation to show that preparing dapson formulations in the claimed spray, lotion or cream formulations, suggested by present rejection. The motivation to prepare the composition in the form of gels, lotions etc., depending on the skin type being treated comes from the teachings of Russell and also from the teachings of Singleton. Therefore, it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapson compositions of '060 or '560 in the form of a spray, lotion or a cream or an ointment, depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired treatment of acne lesions (both types). Applicants' argument that the only expectation of one of an ordinary skill in the art would be that dapson of Osborne will not work to treat non-inflammatory lesions. The argument is not persuasive because it is clear from the Declaration of Lothrop that acne includes both types of lesions and with respect to Sykes, the review states on page 61 that benzoyl peroxide is comedolytic and is more effective when combined with erythromycin (antibiotic), thus suggesting that antibiotics are useful in comedolytic treatment (comedones are basic non-inflammatory lesions –see page 60 of Sykes). Further, on same page 62, Sykes also states that many cases of acne represent a combination of inflammatory and non-inflammatory lesions,

which further supports the examiner's position that dapsonc of Osborne, while treating inflammatory also inherently treats non-inflammatory acne.

Additionally, examiner's response from the advisory action dated 5-25-07 (in response to applicants' arguments of 5-10-07) is repeated here:

In response to the argument that there was no actual use of dapsonc by Osborne for treating acne, Osborne clearly emphasizes that the invention is directed to treat acne (C 3, L 12-16). Further, Osborne references state that in order to treat inflammatory lesions, the active agent has to penetrate past the stratum corneum (C2, L 5-15) and teaches a composition that contains active agent, dapsonc, such that one form of dapsonc is able to cross stratum corneum to treat inflammation and another form of dapsonc (in the same composition) that does not cross stratum corneum. Thus, the composition of Osborne provides treatment for both inflammatory acne and non-inflammatory acne. It is implicit that inflammatory and non-inflammatory lesions co-exist and prior art teaches same compound for the same condition (acne), and furthermore, teaches one part of the composition that is exclusively for crossing stratum corneum and another for above stratum corneum. Accordingly, if applicants' assertion that instant invention is effective for treating acne then for the same reason the formulation of Osborne references is inherently effective for non-inflammatory acne.

Claim Rejections - 35 USC § 112

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 recites the limitation, "wherein the efficacy for treating non- inflammatory acne is inverse to the efficacy for treating inflammatory acne", which is not supported by the specification because applicants nowhere (including the data in Table 1) mention the relationship between treating non-inflammatory acne and its effect on the number of inflammatory acne lesions. While applicants state on page 7 of their response dated 11-2-07 that the data of table 1 supports the inverse relationship, the specification does not clearly disclose to the skilled artisan that the inventors considered the inverse relationship to be part of their invention because other than the results on table 1 applicants have not described such a relationship and the newly added limitation is picked from the general disclosure. *Purdue Pharma L.P.v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). A skilled artisan reading the general disclosure of the instant applicants would not be able to readily conceive that the inverse relationship claimed is a part of the instant invention.

Response to Arguments

Instant claim 27 is amended to recite "wherein said dapsone is applied once a day" and therefore the rejection of claim 27 under this section has been withdrawn

Regarding claim 29, applicants request examiner to consider the guidance provided by the court in *In re Wertheim*, 541 F.2d 257 (CCPA 1976). It is argued that the court's opinion points out, an in ipsius verbis recitation of the inverse efficacy of dapsone for treating non-inflammatory acne and inflammatory acne is not required. It is

argued that one of skill in the art would easily recognize this effect in the first data set of Table 1. Once daily dosing of 1% dapsoe causes the least percent reduction of inflammatory lesions (13%) while the same dosing causes the greatest percent reduction of non-inflammatory lesions (53%). It is argued that this inverse efficacy is immediately clear upon consideration of Table 1; thus, a sufficient description is provided.

Applicants' arguments are not persuasive because the argued relationship with respect to the amount of dapsoe (1%) and the once a day administration is not claimed and the claim includes any amount of dapsoe and any number of applications, for which applicants did not provide any description of inverse relation in treating inflammatory versus non-inflammatory lesions.

It is argued that the Examiner alleged that "...the specification does not clearly disclose to the skilled artisan that the inventors considered the inverse relationship to be part of their invention because other than the results on Table 1 applicants have not described such a relationship and the newly added limitation is picked from the general disclosure." Applicant responds that MPEP 2163.02 states that an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). The descriptive means of the Table 1 data are sufficient to cause one of skill in the art to readily and immediately appreciate the possession of the claimed inverse relationship.

Applicants' arguments are not persuasive because while it is true that an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention, instant specification fails to clearly convey such a relationship for the entire scope of the claim by any of the above means. “[T]he essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). In fact, without any statistical analysis of the results, one cannot conclude that a significant difference between the inhibition of inflammatory and non-inflammatory lesions in the 1% dapsonc twice daily treatment described in table 1 of the instant specification.

Third, Applicants argue that applicant has made clear throughout the instant specification that non- inflammatory acne and inflammatory acne are separate and distinct conditions (see paragraphs [0004]-[0007], [0012] and [0016]), Applicant analyzed inflammatory and non- inflammatory acne separately in Example 2 and showed different effects of dapsonc. It is argued that this inverse efficacy shown in Table 1 and recited in claim 29 is a clear and important distinction between the two types of acne that corresponds clearly with the remaining disclosure of the specification.

Thus, it is argued that the specification conveys with clarity to those skilled in the art that applicant was in possession of the invention in claim 29 as of the filing date. However, the argument is not persuasive because the analysis of whether the specification complies with the written description requirement calls for the comparison of the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. As explained above, example 2 (table 1) is specific to 1% and 5% dapsone with once or twice daily dosing, which is not commensurate with the scope of the claims and the specification nowhere states or implies the claimed relationship for the entire scope of the claim. Therefore, the rejection has been maintained.

In response to the amendment, the following rejection of record has been withdrawn:

Claims 1,4, 7-22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
December 6, 2008